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UNION OF SOVIET SOCIALIST REPUBLICS
USSR STATE COMMITTEE
ON INVENTIONS AND DISCOVERIES

# INVENTOR'S CERTIFICATE

## No. 1251912

On the basis of the authority granted by the Government of the USSR, the State Committee on Inventions and Discoveries has issued the present inventor's certificate for
**"treatment modality of open fistulas"**

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The Inventor's Certificate is effective throughout the territory of the USSR.

Committee Chairman [signature]
Division Head [signature]

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# SPECIFICATION OF INVENTION
FOR INVENTOR'S CERTIFICATE

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(71) The S.M. Kirov State Medical Institute in the city of Gorky
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(53) 611.3-007.253 (088.8)
(56) N.T. Emuhvari, External tamponade of biliary fistulas using a foam sponge. Materials of the academic session of practicing physicians of Abkhazia. Sukhumi, 1970, p. 67.

Alexander-Williams J, Irving M. Intestinal fistulas. Bristol—London—Boston, 1982, 149, 201.

(54) (57) TREATMENT MODALITY OF OPEN FISTULAS, including the obturation of the fistula cavity or lesion with a polymer material and its drainage, characterized in that with the goal of decreasing the number of complications by reducing traumatization of the wound and providing an active mobility regimen for the patient, the obturation is carried out using a foam sponge into which a drain is introduced and aspiration with a vacuum degree of 0.1–0.5 kg/cm$^2$ is conducted.

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The invention pertains to medicine, particularly to surgery, and may be utilized for the treatment of fistulas of the gastro-duodenal zone.

The goal of the invention is to decreasing complications by reducing traumatization of the wound and providing an active mobility regimen for patients.

The treatment modality is carried out as follows.

Using scissors, shape the foam which has been kept in antiseptic solution into a stype of a size and shape corresponding to the cavity space of the fistular opening. With a single suture, affix a drainage tube containing multiple perforations to the foam stype, burying it within the foam's center. The compressed stype is inserted into the fistular opening with the help of forcepts. The stype is uncurled to fully cover the fistular opening, which is then covered with an antiseptic dressing. Using a standard suction apparatus, conduct active aspiration with a negative pressure of 0.1–0.5 kg/cm$^2$.

The negative pressure's lower range limit is determined empirically. It has been observed that the use of 0.5 kg/cm$^2$ active aspiration, does not have a harmful effect on the organs of the abdominal cavity when the aspiration is conducted through foam. 0.1 kg/cm$^2$ active aspiration is sufficient with purely biliary and pancreatic fistulas in the event of a relatively tidy wound, where there is no possibility of necrosis or the adsorption of large amounts of fibrin on the sponge, and the volume of draining fluids does not exceed 1 L. It is advisable to use the upper range of the active aspiration in combination with the defluvium of active biological fluids taken by mouth (in the case of a lack of flat sutures following a gastrectomy, inadequate gastroenterostomy, gastro-duodenostomy, or pancreatojejunal anastomosis), when during fluid intake the concomitant defluvium may exceed 50–80 ml/min.

Higher negative pressure within the specified range should be used in the beginning of treatment as well in the even of purulo-necrotic wounds. Moreover, despite the fact that part of the foam's surface might be covered with fibrin and cankers, the application of negative pressure on voids is compensated [illegible] part of the foam sponge. Aspiration remains adequate. Employing negative pressure of more than 0.5 kg/cm$^2$ is inadvisable, especially with tidy wounds having a small amount of defluvium (up to 1 L), as it causes excess granulation in the foam and its excessive traumatization during the changing of the rubber model. A pressure range of 0.5 kg/cm$^2$ is sufficient for the aspiration of 3 L of liquid in 1 hr.

A negative pressure range of 0.1–0.5 kg/cm$^2$ is safe, and in each case the choice of treatment in this range can be individual for each patient. The aspiration regimen may be corrected during the course of treatment.

The collection of evacuated fluids during the course of treatment facilitates the management of the conducted transfusion therapy. Every day with the purpose of improving the germicidal effect and the reparative processes of the anhydration of the tissue of the fistular opening, the patient undergoes a session of ultrasound therapy on the wound. For this purpose, the suction apparatus is turned off and the foam stype is amply saturated with antiseptic via the drainage tube. Using the apparatus "Sterzhen 1" 0.5 MW/cm$^2$ of ultrasound is delivered through the nozzle tip for the duration of 15 minutes. The dressing must be changed once every four days for the purpose of changing the foam stype, which is modeled each time to correspond with the shrinking area of the fistular opening (cavity).

*Example 1.* Patient P., age 22. Has been diagnosed with: Leak of the duodenal stump following a 2/3 partial gastrectomy for a duodenal ulcer, complicated by profuse bleeding. Severe post-hemorrhagic anemia.

From the patient's medical history it has been learned that on May 29, 1983 the patient presented with secondary profuse bleeding from a duodenal ulcer. The same day, the patient underwent a partial 2/3 gastrectomy with atypical duodenal coverage at the level of bleeding, performed in the regional hospital by a physician of the medical aviation unit.

The post-operative period saw a complication on the fifth day due to a leak of the duodenal stump. For twenty-four hours after the operation the utflow of bile along the drainage tube ceased. It began to flow past the drainage tube and from the wound into the dressing. The dressing was changed 18 times in twenty-four hours. Despite this, progressive peracute maceration of the abdominal wall began to take place. Sutures on the wound began to erupt. Hypovolia intensified. Parenteral alimentation was made difficult due to the presence of acute allergic reactions (transfusional pyrexia).

The following was established after examination: [on the entire] anterior abdominal wall and particularly of the anticardium, where the wound following the [upper midline abdominal section] is located, the skin exhibits marked maceration and weepage, and the slightest touching of the skin causes

very sharp pain.. A rubber drainage tube, which is not working, is found in the center of the post-surgical wound. Abundant bile is flowing past the drainage tube through the wound. The outflow of bile intensifies at the slightest change in the position or movement of the patient, which is a clear indication of inadequate bile outflow. Persistant high fever (to 39°C). The lower abdomen is [intact]. Blood tests results reveal anemia and [a shift of] the white blood cell differential [to the left].

The patient is taken for a dressing change. Four sutures are removed from the wound (from the skin and aponeurosis), the drainage tube is removed. The wound is partially separated. In the process, it is determined that in the right subhepatic region there is a cavity circumscribed by the intestines and omentum, containing nearly 200.00 of cloudy bile with flocks of fibrin. The bile is removed and the cavity is dried. The bottom of the cavity contains a mass of fibrinous deposits and an abundance of cankers, amongst which a defect in the duodenal ulcer of up to 0.4x0.4 cm. is observed, from which there is a constant outflow of bile. The dimensions of the cavity are 10x8x6 cm.

In accordance with the dimensions of the cavity, a foam model is prepared into which a perforated polyvinyl chloride drainage tube is inserted and affixed with a single suture. The compressed stype is inserted into the cavity and placed in the subhepatic region. Active 0.1 $kg/cm^2$ aspiration is begun. Aspiration is adequate, there is no bile ingress to the skin. The wound is left unbandaged and is being treated in the open manner. Within 24 hours, 1200.0 [units] of bile was drained. However, in the following 12 hours, bile was again found on the skin and at the same time, there was a dramatic reduction in the amount of bile coming through the drainage tube (by 200.0 [units] over 12 hours). The pressure was increased to 0.5 $kg/cm^2$. Aspiration once again became adequate. The amount of bile drained over 24 hours was 1200.0 [units].

On the third day, during the changing of the foam model, the reason for the interference with the adequate collection of bile became clear. The entire foam sponge was covered with fibrous necrosis, which interfered with its absorption capacity to a degree of 0.1 $kg/cm^2$. Increasing the negative pressure to 0.5 $kg/cm^2$ resulted in the reintroduction of adequate aspiration. The collected filtered bile was given to the patient by mouth. Two weeks later, before the start of aspiration the patient's condition markedly improved. He became transportable, the maceration of the skin disappeared, and the patient was transferred to the district hospital, where active 0.5 $kg/cm^2$ aspiration was continued for another 8 days. During this period, the volume of draining bile was reduced to 200.00. The cavity in the subhepatic region shrank to half its size and became filled with abundant granulation tissue.

The replacement of the foam model coupled with the application of negative pressure of 0.5 $kg/cm^2$ for the duration of 4 days, markedly increased growth of granulation tissue into the foam, resulting in excessive bleeding from and trauma to the granulation tissue during the changing of the foam insert. Therefore, the rate of active aspiration was reduced to 0.1 $kg/cm^2$. The growth of granulation tissue into the foam has practically ceased, the bleeding of granulation tissue during dressing changes is markedly reduced, and in connection with the reduced amount of out-flowing bile, the rate of bile collection remains complete. The aspiration system continued to work at this rate and in this manner for another 7 days, after which point the outflow of bile ceased altogether. The foam [sponge] is removed from the wound, aspiration is stopped. A medium-sized vaseline-soaked gauze trailer is inserted into the wound. On July 18, after the wound is fully healed, the patient is discharged. Followed up a year later, works as a driver, no complaints. No recurrence of the fistula is observed.

*Example 2.* Patient Sh., born 1940, present in the clinic from 11/10/82 to 01/27/1983.

On 12/04/82, a pancreaticoduodenal resection is performed due to pseudo-tumorous pancreatitis. The post-operative period was complicated by the inefficiency of the pancreatic inosculation, which resulted in the formation of an external pancreatic fistula. For the duration of eight days, passive drainage was carried out, and due its ineffectiveness treatment by the suggested method was begun.

Under local anesthesia, the post-operative wound was widened along the removed drainage to 2 cm in length and 15 cm in width. A cavity was found in the abdominal region, circumscribed by the loops of the small intestine. The inflow of pancreatic juice was occurring between the loops of the intestine on the bottom of the cavity. Obturation of the wound is conducted using the modeled foam [sponge]. Aspiration at a rate of 0.1 $kg/cm^2$ is begun. Within 24 hours 600 ml of pancreatic juice are evacuated. By the third day the mobility regime is extended, the patient is permitted to sit and walk around his room. Daily sessions of ultrasound therapy were carried out. Active aspiration was reinstituted following each session. Dressing changed once every four days, the wound became cleaner and filled with granulation tissue. By the $17^{th}$ day the amount of pancreatic juice was reduced to 30 ml, the fistular opening markedly went down in size. Active aspiration was stopped and a dry antiseptic dressing was applied. On the $28^{th}$ day, the patient was discharged with the wound fully healed.

This method passed successful clinical trials and is recommended for surgical practice.